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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,333	01/16/2001	Samuel G. Armato III	198069US-20	2550

22850 7590 08/12/2004

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EXAMINER

AZARIAN, SEYED H

ART UNIT	PAPER NUMBER
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2625

DATE MAILED: 08/12/2004

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/759,333

Applicant(s)

SAMUEL G. AARMATO

Examiner

Seyed Azarian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 15-24, 27-35, 36/1-7, 36/15-24, 36/27-35, 37/1-7, 37/15-24, 37/27-35 is/are rejected.
- 7) ☒ Claim(s) 8-14, 25, 26, 36/8-14, 25, 26 and 37/8-14, 25, 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12</u> . | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

1. Applicant's arguments, filed, 5/17/2004, see page 2 through 6, of remarks with respect to the rejection of claims 1-37 have been fully considered but they are not persuasive.

2. Applicant's argues in essence regarding claim 1, that Townsend does not teach, "generating three-dimensional segmented lung images".

Contrary to the applicant's assertion, Townsend discloses, image display offers a two-dimensional, slice by slice (segment) approach to the display of a **three-dimensional volume data** set, the 3D display computer offers interactive 3D graphics of anatomical structures, such as tumor masses (column 14, lines 31-43).

In response to Applicant's argument regarding claim 1, that Townsend does not teach, or suggest, "determining three-dimensional lung nodule candidates from the three-dimensional segmented lung volume images, including identifying structures".

The Examiner disagrees and indicates, Fig. 10A-C, demonstrate a large lesion in the upper quadrant of right lung (column 19, lines 18-28), also a smooth 3D surface to the exterior of the skin layer as determined from image by comparing the outline of the body as determined from CT, the missing volume is estimated. This "volume is added to the CT image and set to the "average linear attenuation coefficient" (column 22, lines 3-19), and finally 3D displaying of functional structures, such as tumor masses (column 14, lines 31-47).

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Furthermore, in response to applicant's argument, regarding claim 1, that Townsend does not teach, "deriving features from the three-dimensional lung nodule".

Contrary to the applicant's assertion, Townsend discloses, Fig. 9, displaying computer 3D, graphics of "anatomical structures, functional structures such as tumor masses and generation spiral, or helical, CT tomograph, (column 14, lines 31-47), also detect and distinguish significant uptake that the nodules is malignant or non-malignant (column 13, line 58 through column 14, lines 4).

As to claim 1, the Applicant alleges that Townsend does not teach or suggest the "eliminate false positive nodule candidates from the nodule candidates".

The Applicant is respectfully reminded that the rejection of the claim 1 is a combination of two references not just Townsend, references cannot be argued individually to show nonobviousness (see MPEP 2145 (d)). Townsend is modified by Jyh-Shyan Lin.

Jyh-Shyan Lin teaches (Reducing False-Positives in Lung Nodule Detection), the research efforts are aimed at increasing the true-positive fraction while decreasing the false-positive fraction (page 1842, first paragraph).

Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention was made to modify the method of the Townsend invention according to the teaching of Jyh-Shyan Lin because it provides information by reducing the numbers of false-negative and false-positive diagnoses of malignancies which decreasing patient morbidity as well as the number of surgical biopsies to achieve an accuracy and cost.

In response to applicant's argument that obviousness has not been established, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 1-7, 15-24, 27-35, 36/1-7, 36/15-24, 36/27-35 and 37/1-7, 37/15-24, 37/27-35, are rejected under 35 U.S.C. 103(a) as being unpatentable over Townsend et al (U.S. patent 6,490,476) in view of Jyh-Shyan Lin (an application of convolution neural network: reducing False-Positives in lung nodule detection--1995).

Regarding claim 1, Townsend discloses a method for automated detection of lung nodules in computed tomography (CT) image scans, comprising;

generating two-dimensional segmented lung images by segmenting a plurality of two-dimensional CT image sections derived from said CT image scans (Fig. 5A, 5B and 5C, column 17, lines 33-41, the original CT image and corresponding images after segmentation);

generating three-dimensional segmented lung volume images by combining said two dimensional segmented lung images (column 14, lines 31-43, generating a three-dimension from two-dimensional slice).

determining three-dimensional lung nodule candidates from said three-dimensional segmented lung volume images, including, identifying structures within said three dimensional segmented lung volume images that meet a volume criterion (Fig. 10A-C, demonstrate a large lesion in the lung, also column 22, lines 15-19, volume is added to the CT image and set to the average linear attenuation coefficient);

deriving features from said lung nodule candidates (Fig. 9, column 14, lines 31-47, anatomical structures, functional structures and generation spiral, CT tomograph);

and detecting lung nodules by analyzing said features (column 13, line 58 through column 14, lines 4, distinguish that the nodules is malignant or non-malignant).

However Townsend is silent about "eliminate false-positive nodule". On the other hand Jyh-Shyan Lin teaches the research efforts are aimed at increasing the true-positive fraction while decreasing the false-positive fraction (page 1842, first paragraph).

Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention was made to modify method of Townsend invention according to the teaching of Jyh-Shyan Lin because it provides information by reducing the numbers of false-negative and false-positive diagnoses of malignancies which decreasing patient morbidity as well as the number of surgical biopsies to achieve an accuracy and cost.

Regarding claim 2, Townsend discloses the method of Claim 1, wherein said step of generating said segmented lung images comprises the steps of: generating two-dimensional segmented thorax images by segmenting said plurality of two-dimensional CT image sections, including, applying gray-level thresholds to said CT image sections to determine thorax region contours therein (Fig. 4A, 4B, 5A and 5B, illustrates region of thorax, and column 17, lines 23-41, region of pixels classified by thresholding);

generating said two-dimensional segmented lung images by segmenting said segmented thorax images, including, applying gray-level thresholds to said segmented thorax images to determine said lung region contours therein (Fig. 10A and 10B, images of lung).

Regarding claim 3, Townsend discloses the method of Claim 2, wherein said step of generating said segmented thorax images further comprises, segmenting the trachea and main bronchi from said segmented thorax images using region growing (Fig. 13 A, column 19, line 60 through column 20, line 11, illustrated trachea).

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Regarding claim 4, Townsend discloses the method of Claim 2, wherein said step of generating said segmented lung images further comprises, segmenting the diaphragm from said segmented lung images using diaphragm analysis (column 21, lines 45-58, movement of the chest wall and abdomen).

Regarding claim 5, Townsend discloses the method, wherein said step of generating said segmented lung volume images comprises, generating said segmented lung images at a plurality of gray levels thresholds; and combining said segmented lung images to generate segmented lung volume images at a plurality of gray levels corresponding to said gray level thresholds (Fig. 5, column 17, lines 24-41, classified pixel, using threshold).

Regarding claim 6, Townsend discloses the method of Claim 5, wherein said step of identifying said structures comprises, grouping a pixel from a given segmented lung image with one or more pixels therein one or more pixels from a segmented lung image above said given segmented lung image and one or more pixels from a segmented lung image below said given segmented lung image to determine a structure (column 18, lines 14-30 comparison of lesion in the lung).

Regarding claim 7, Townsend discloses the method of Claim 6, further comprising, using region erosion on said nodule candidates to determine if said nodule candidates comprise one or more smaller structures (column 18, lines 52-63, the contrast of the small lesion).

Regarding claim 22, Townsend discloses the method, further comprising, using region erosion on said nodule candidates to determine if said nodule candidates comprise one or more smaller structures (column 8, lines 39-58).

Regarding claim 32, Townsend discloses a method for automated analysis of features of lung nodules in computed tomography (CT) image scans, comprising, generating two-dimensional segmented lung images by segmenting a plurality of two dimensional CT image sections derived from said CT image scans, generating three-dimensional segmented lung volume images by combining said two dimensional segmented lung images, determining features from said nodule candidates including at least one of structure volume, sphericity, radius of equivalent sphere, maximum compactness, maximum circularity, maximum eccentricity, mean gray level within structure, standard deviation of gray level and gray-level threshold at which. structure volume first decreases below an upper volume bound (see claim 1, also column 13, lines 58-67, normal or non-malignant tissue process by adopting a threshold, also column 14, lines 31-47, anatomical structures, functional structures and generation spiral, CT tomograph).

Regarding claims 16, 20 and 23-24, it recites similar limitation as claims 1 and 2, are similarly analyzed.

Regarding claims 15, 27-31, it recites similar limitation as claim 1, are similarly analyzed.

Regarding claims 17-19 and 21, it recites similar limitation as claims 1, 2 and 6, are similarly analyzed.

Regarding claims 33-37, it recites similar limitation as claims 1 and 14, are similarly analyzed.

Allowable Subject Matter

5. Claims 8-14, 25 and 26, 36/8-14, 25, 26 and 37/8-14, 25, 26 are objected as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitation of the base claim and any intervening claims.

Conclusion

6. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Seyed Azarian whose telephone number is (703) 306-5907. The examiner can normally be reached on Monday through Thursday from 6:00 a.m. to 7:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh Mehta, can be reached at (703) 308-5246. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR.

Status information about the PAIR system, see [http:// pair-direct.uspto.gov](http://pair-direct.uspto.gov). Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Seyed Azarian

Patent Examiner

Group Art Unit 2625

July 28, 2004



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